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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/807,704 | 07/25/2001 | Stig Jansson | CU-2513 RJS | 2557 |

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| EXAMINER | |
|---|---|
| WINSTON, RANDALL O | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/807,704 | JANSSON ET AL. | |
| | Examiner | Art Unit | |
| | Randall Winston | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *53 and 54* is/are allowed.

6)☒ Claim(s) *35-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 07/25/2008. Applicant's amendment has overcome Examiner's 112, second paragraph, rejection. Claims 35-54 have been examined on the merits.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-52 stand rejected under 35 U.S.C. 1039a) as being unpatentable over Jannson et al. (NO 933009 - full English translation thereof) in view of Keyes (US 4,713,335) for the reasons set forth in the previous Office Action which are restated below.

Applicant claims an improved oil separation process for production of a composition free of denatured proteins from a material comprising lipids and proteins, said material having a biological origin, the process comprising the steps of predetermining a denaturing temperature of a material comprising lipids and proteins (i.e. predetermining temperature is determined by visual observation and/or viscosity measurement), freezing and mechanically treating the material (also adding pretreatment compounds prior to mechanically treating), heating the material to a working temperature, wherein said working temperature is below the denaturing

temperature and separating a composition comprising protein and at least one of the group consisting of fat and lipid, said composition being free of denatured proteins.

Jansson et al teach (see entire English translation of this document) a process for separating elements from the claimed biological material compound and/or composition (i.e., fish or marine material) to obtain high yields of non-denatured protein (i.e. free of denatured proteins), fats or lipids and intrinsically producing grax and trace elements when performing Jansson's separation step whereas Jansson's claimed process would also intrinsically produce the claimed composition comprising non-denatured protein (i.e. free of denatured proteins) and at least one of the group consisting of fat and lipid when such steps are performed as the steps of freezing and mechanically treating the biological material (i.e. please note mechanically treating by grinding and also the reference statesone of ordinary skill in the art would add pretreatment compounds such as solvents and/or enzymes because enzymes protect the lipids against oxidation within the process and the reference also states adding antioxidants wherein the process, see, e.g. page 3 and 4) at the same claimed freezing temperature interval (i.e., freezing at –6 degree Celsius); subsequently heating the biological material to a temperature as not to denature the protein contained within the biological material (i.e. please note on page 9 of Jansson et al's specification, it states that the heating should be done at low temperatures not to denature the protein), and then separating and isolating high yields of lipids, fats or non-denatured protein whereas Jansson's process intrinsically produce the claimed composition comprising non-denatured protein (i.e. free of denatured proteins) and at least one of the group

consisting of fat and lipid. Jansson's process is also done under a condition of a vacuum.

Jansson et al. do not expressly teach claims 49-50 of predetermining the denaturing temperature of the material is determined by visual observation (i.e. claim 49) and/or viscosity measurements (i.e. claim 50).

It would have been obvious to one of ordinary skill in the art at the time the invention was created to modify Jansson et al's process to include the predetermining step of visual observation to determine the denaturing temperature of a material because visual observation would be an intrinsic feature within '009 to aid in monitoring the temperature within the process in order not allow the protein to become denatured. (please note: predetermining the denaturing temperature by visual observation prior to performing the other claimed steps, especially the heating step in order not to denature the protein would be an intrinsic feature within '009 process. On page 9 lines 2-5 of '009, it states that low-temperatures should be used within its process not to denature the proteins. Thus, a predetermining step would be an intrinsic feature within '009 process because '009 discloses monitoring its process's temperature by utilizing a low temperature for the purpose of not to denature the protein.)

Furthermore, Keyes beneficially teaches (see, e.g. column 5 lines 29-35) that viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jansson et al.'s process to include the disclosure of viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material as taught by Keyes' because the combined teachings would create a method of separating elements from a material wherein the elements separated do not contain denatured proteins. The adjustment of conventional working conditions (e.g the heating step is performed continuously and/or semi-continuously, the isolation step and the freezing rate and/or time period), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan. Moreover, as the references indicate the various different steps used by the claimed method is result variable, therefore, they could be routinely optimized by one of ordinary skill in the art of practicing the invention disclosed by the references. (e.g. the ordered pretreatment steps, the order of the predetermining step, especially before heating and the ordered mechanically treating steps occurs before said freezing step) (Please note the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330-CCPA 1946) MPEP 2144.04)

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argument has been carefully considered but it is not deemed persuasive. Applicant argues that Applicant can find nothing within Jannson and/or Keys that teaches and suggests, *inter alia*, adding pre-treatment compound to the material prior to mechanically treating the material. Since Jannson doesn't teach a pre-treatment compound, it follows that Jannson and/or Keys are silent with regards to pre-treatment compound that include such things as enzymes, a solvent, an emulsion-bursting material, and an emulsion-inhibiting solution.

Although Applicant argues that Applicant can find nothing within Jannson and/or Keys that teaches and suggests, *inter alia*, adding pre-treatment compound to the material prior to mechanically treating the material, Applicant argument is not found persuasive because Jannson discloses on page 3 and 4 that one of ordinary skill in the art would add pretreatment compounds such as solvents and/or enzymes because enzymes protect the lipids against oxidation within the process.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

Claims 35-52 are not allowed.

Claims 53-54 are allowable over the prior art of record because a process for an improved separation process for production of oil from a biological material via the overall steps defined by instant claim 53, as well as instant claim 54, is neither taught nor reasonably suggested by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655